

REASONS FOR PRE-APPEAL BRIEF REVIEW

In the Office Action mailed July 25, 2006 (hereinafter, the “Office Action”), Claims 1 and 3-15 were finally rejected. Claims 1, 3-7, and 10-15 were rejected under 102(b) as allegedly all being anticipated by U.S. Pat. No. 5,342,631 to Yotka et al (hereinafter “Yotka”. Claims 1, and 3-15 were rejected under 103(a) as allegedly obvious over Yotka in view of U.S. Patent No. 4,824,681 to Schobel et al (hereinafter “Schobel”). In the following discussion Applicant has focused on specific aspects of the claimed invention which are clearly not taught or suggested by the cited references. This does not preclude Applicant from arguing additional deficiencies in the cited references during any later Appeal proceedings or prosecution.

The Claimed Invention

As now claimed, the Applicant is claiming a sugar-free soft chew tablet composition comprising: a reheatable composition that includes

- a) a mixture of at least two polyols present in an amount from about 15 to 80% by weight, said polyols being selected from the group consisting of hydrogenated starch hydrolysate, maltitol, lactitol and mixtures thereof;
- b) an emulsifier system present in an amount from about 1.0 to 30% by weight;
- c) water in an amount from 0 to 15% by weight;
- d) an active agent in an amount from 0.1 to 70% by weight that is added to the reheatable composition either upon cooling or after the composition has been cooled and later reheated to form the soft chew; and
- e) optional components comprising colors, flavors and binders.

As set out in the above claim, the present invention is drawn to a sugar-free soft-chew

tablet composition which comprises a reheatable composition. As described in the originally filed specification and discussed in the previously submitted office action responses, the reheatable composition of the present invention can be cooled, heated again to incorporate additional ingredients, and subsequently re-cooled without damaging or altering the characteristics of the composition, e.g. texture, consistency, etc.

Rejection under 35 U.S.C. § 102(b) over Yatka

Applicants submit that the composition taught in Yatka is not reheatable as required by the presently pending claims. Yatka teaches a petroleum wax-free chewing gum containing a special petroleum wax-free gum-base and nancoriogenic oligosaccharaides. The Examiner has asserted that the cited reference teaches a composition with “the same ingredients as claimed in the same amounts as claimed” and therefore “the reference composition would inherently have to have the same reheatable characteristic if applicant’s composition functions as claimed.” The Applicant’s recognize that Yatka may teach a composition which has some of the same ingredients as required in the present claims; however, the compositions taught in Yatka also require a petroleum wax-free gum-base. As discussed in the previously submitted office action of April 17, 2006, the Applicant’s assert that the inclusion of the petroleum wax-free gum-base in the compositions of Yatka renders the compositions, as with other gum products, un-reheatable. Such an assertion is supported in the declaration by S. Rao Cherukuri under 37 C.F.R. 1.132 which was submitted on the same date as the office action and which discusses the un-reheatable nature of gums and gum products, which includes the compositions taught by Yatka.

The Examiner has asserted that because Yatka teaches compositions which share at least some components of the present invention they “inherently” share the same characteristics of the compositions of the present invention, namely reheatability. However, Applicants contend that mere presence of some shared elements is insufficient to conclude that the properties vitally claimed as a part of the present invention would also be inherently found in this reference. Rather, to conclude inherency of activity or property, the identical compositions would have to be expressly taught. This is not the case with Yatka. Nothing in Yatka expressly teaches assembling the ingredients mentioned into a composition that is identical to the present invention. Rather, the ingredients are merely mentioned at various locations throughout the reference and the Examiner has used hindsight to assemble them into a composition overlapping the claimed composition.

The case law under 35 U.S.C. 102(b) is well-settled. For a reference to anticipate a claim, the reference must show each and every element of the claim, either explicitly or inherently. “Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981). In addition, for a reference to be anticipatory by way of inherency, the claimed invention must necessarily be the “natural result” of the teachings of the prior art. *Id.* The Examiner has implicitly conceded that the reference does not explicitly anticipate the claimed invention. Applicants have, by way of a Declaration by the inventor, asserted that one of ordinary skill in the art would not consider that the claimed invention necessarily flows from or is the “natural result” of the teachings of the prior art. The Examiner has not provided any substantive basis in rebuttal. Therefore, Applicants

respectfully submit that this rejection under 35 USC 102(b) is untenable and should be withdrawn.

Furthermore, Yatka requires the use of a wax-free gum base. The inclusion of such an ingredient actually makes the compositions of Yatka inherently distinct from the claimed compositions of the present invention as this ingredient alters the characteristics of the compositions as a whole and renders them non-reheatable. The Applicants assert that the reheatable nature of the presently claimed composition is an element of the composition, which element is not taught or found in Yatka. Therefore, Yatka fails to teach each and every element of the pending claims. As such, the Applicant respectfully submits that Yatka clearly does not anticipate the claimed invention for at least the reasons outlined above.

Rejection under 35 U.S.C. § 103(a) based on Yatka in view of Schobel

The inventive focus of Schobel is an extended release sweetener composition comprising solid particles of a sweetening agent coated with a coating material. The coating material can include a hydrophobic polymer and a hydrophobic plasticizer. The reference further teaches that the sweetening agent can be used in compositions that are held in the mouth, such as gum, for a long time in order to utilize the full benefit of the lengthened sweetening effect provided by the sweetening agent. However, nothing in the '681 reference teaches or suggests a reheatable composition of any kind as required by the claims of the present invention. As discussed above, Yatka also fails to teach the required reheatable composition. Even if one of skill in the art somehow were motivated (the Examiner has presented no argument pointing to such motivation) to combine the references, such combination still fails to produce the claimed reheatable

composition. Therefore, individually and collectively the two cited references fail to teach or suggest each and every element of the presently pending claims. As such, it is respectfully requested that this rejection be withdrawn and the pending claims be allowed.

Accordingly, Applicant respectfully requests that the rejections be withdrawn and the claims be passed to issue.

CONCLUSION

In view of the foregoing, Applicant believes that the present rejections are unsustainable and should be withdrawn. Therefore, Applicant respectfully requests that the prosecution be reopened and/or the claims be allowed. If any impediment to the allowance of these claims remains after consideration of the above remarks, and such impediment could be resolved during a telephone interview, the Examiner is invited to telephone Mr. David Osborne, at (801) 566-6633, to address such issues as expeditiously as possible.

Dated this 26th day of December, 2006.

Respectfully submitted,

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